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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Raul G. Barletta

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09/16/2005

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/759,287

Applicant(s)

BARLETTA ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9-5-03, 3-22-03, 2-28-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Response to Final Office Action, received 5 September 2003, is acknowledged. Claims 1-14 and 43-53 have been canceled. Claims 15, 28, 29, and 42 have been amended.
2. Applicants' Power of Attorney, received 22 March 2003, is acknowledged.
3. Applicants' letter of status inquiry, received 28 February 2005, is acknowledged.
4. Claims 15-42 are pending and under consideration.

### **Rejections Withdrawn**

5. The rejection of claims 15-42 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccines, is withdrawn in light of the amendment of the claims.

### **Specification**

6. The disclosure, page 12, is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.
7. The disclosure is objected to because of the following informality: page 23, line 1, "Amikcin" should be "Amikacin". Appropriate correction is required.

### **Response to Amendment**

8. The amendment to claim 23 filed on 5 September 2003 does not comply with the requirements of 37 CFR 1.121(c) because the claim has been changed back to its original form, i.e., the form prior to the amendment received 10 September 2002, without appropriate markings. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is

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being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

### **Claim Rejections - 35 USC § 112**

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 15-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-41 are drawn to a composition comprising a carrier and at least one nonvirulent strain of bacteria, wherein said nonvirulent strain of bacteria has at least one mutation in its genome. The process for producing the mutated nonvirulent strain of bacteria comprises culturing said bacteria in the presence of an antimicrobial agent that kills growing but not nongrowing bacteria, and selecting surviving bacteria.

The specification, page 11, proposes that the culture conditions comprise broth or medium to which an antimicrobial is added at a concentration that exceeds the MIC. However, the only example put forth, Ex. 4, does not utilize broth, but a salt solution to produce nongrowing conditions. Following incubation in this nongrowth permissive conditions, the bacteria are then plated onto a medium which allows growing. Figure 3 indicates that even under the salt solution, nongrowing environment, the antimicrobial BAY Y 3118 did kill the nongrowing cells, e.g., 20X MIC.

Therefore, it is unclear if the differentiation of "growing" or "nongrowing" cultures of bacteria are to be based upon the speculative language on page 11, or the example 4 which uses a salt solution instead of culture medium for the differentiation. Also, it is unclear if the amount of antimicrobial agent is to the any level, or, based upon page 11, any concentration that exceeds the MIC, or if the amount of antimicrobial is to be adjusted between MIC and some upper limit which does kill bacteria even under "nongrowing" conditions, e.g. the 20X concentration of BAY Y 3118.

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Claims 29-41 are drawn to a composition comprising a carrier and at least one bacterial virulence determinant, wherein said virulence determinant is determined by procedures identical to those described, *supra*, for producing mutated nonvirulent strains of bacteria and therefore the claims are unclear for the same reasoning.

Claim 28 is drawn to a composition comprising a carrier and at least one mutant nonvirulent strain of *M. paratuberculosis* wherein said *M. paratuberculosis* is produced by a process comprising mutating a strain of *M. paratuberculosis*, infecting macrophages with the mutated strain, culturing the infected macrophages in the presence of fluoroquinolone or D-cycloserine, and selecting surviving nonvirulent *M. paratuberculosis*.

As discussed above, it is unclear if culture of the infected macrophages in the antimicrobial utilizing any concentration that exceeds the MIC for the antimicrobial, or if the amount of antimicrobial is to be adjusted between MIC and some upper limit, e.g., 5X, which does kill bacteria even under "nongrowing" conditions.

Claims 42 is drawn to a composition comprising a carrier and at least one bacterial virulence determinant, wherein said virulence determinant is determined by procedures identical to those described, *supra*, for producing mutated nonvirulent strains of bacteria and therefore the claims are unclear for the same reasoning.

### **Conclusion**

11. No claims are allowed.

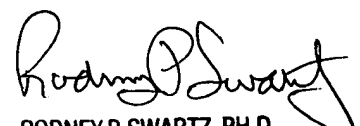
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

September 12, 2005